



## SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

Page 1 of 65 pages

1. Purchase Authority: Public Law 92-218 as amended			
2. <b>Request For Proposal (RFP) Number:</b>  N02-CM-57030-45	3. <b>Issue Date:</b>  03/03/2006	4. <b>Just In Time</b> [x ] NO [ ] YES See Part IV Section L	5. <b>Set Aside:</b> [x ] NO [ ] YES See Part IV Section L

6. TITLE: Synthesis of Non-GMP Small Molecules

7. ISSUED BY:  Office of Acquisitions National Cancer Institute National Institutes of Health Executive Plaza South, Room 6052 6120 EXECUTIVE BLVD MSC-7193 BETHESDA MD 20892-7193	8. SUBMIT OFFERS TO:  See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
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9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1 until 3:00 PM local time on 05/03/2006. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043."

10. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY AS STATED IN ATTACHMENT 1. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH SUBPARAGRAPH (c)(3) OF FAR CLAUSE 52.215-1, ENTITLED, "INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION" LOCATED IN SECTION L.1. OF THIS SOLICITATION.

11. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract.  
(<http://www.ccr.gov>)

12. FOR INFORMATION CALL: Kathleen E. Giuliano  
PHONE: (301)435-3821/FAX: (301)402-6699  
COLLECT CALLS WILL NOT BE ACCEPTED.  
ALL QUESTIONS MUST BE MADE IN WRITING BEFORE APRIL 19, 2006 TO: [giuliank@mail.nih.gov](mailto:giuliank@mail.nih.gov)

13. Table of Contents on following page.

MaryAnne Golling  
Contracting Officer  
Office of Acquisitions  
National Cancer Institute

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## PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

## **SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

### **ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

This project is for the development of novel synthetic and characterized natural products as potential anti-cancer agents. This mission provides essential synthesis support for the early drug development.

### **ARTICLE B.2. PRICES/COSTS**

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

### **ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS**

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

### **ARTICLE B.4. ADVANCE UNDERSTANDINGS**

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

## **SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**

### **ARTICLE C.1. STATEMENT OF WORK**

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated 12/6/2005, attached hereto and made a part of this Solicitation (See Section J - List of Attachments).

### **ARTICLE C.2. REPORTING REQUIREMENTS**

- a. Technical Progress Reports

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award.

For proposal preparation purposes only, it is estimated that 2 copies of these reports will be required as follows:

- (x) Monthly
- ( ) Quarterly

- ( ) Semi-Annually
- (x) Annually
- ( ) Annually (with a requirement for a Draft Annual Report)
- (x) Final - Upon final completion of the contract
- ( ) Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

b. Other Reports

1. Special Business Reports

Upon request, special cost reports with breakdown of expenses may be needed by the Project Officer and shall be provided when requested.

2. Invention Reporting Requirement

All reports and documentation required by FAR Clause 52.227-11, including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the Contracting Officer.

The annual utilization report shall be submitted in accordance with ARTICLE F.1. DELIVERIES of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the following address:

Contracting Officer  
National Institutes of Health  
National Cancer Institute, OA  
EPS, Room 6052  
Bethesda, Maryland 20892-7193

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (<http://www.iedison.gov>), or by contacting the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH.

## **SECTION D - PACKAGING, MARKING AND SHIPPING**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

## SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Project Officer is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at the National Cancer Institute, Developmental Therapeutic Program, Executive Plaza North, Room 8030, Bethesda, MD 20891-7193.
- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

## SECTION F - DELIVERIES OR PERFORMANCE

### ARTICLE F.1 DELIVERIES

- a. Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the services specified in the Delivery Schedule which are described in SECTION C of this contract.
- b. Deliveries required by the contractor shall be made F.O.B. destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984) to the address/addressee listed below:

#### DELIVERY POINT:

National Institutes of Health  
National Cancer Institute  
Executive Plaza North, Room 8030  
6139 Executive Blvd, MSC 7193  
BETHESDA MD 20892-7193

- c. Unless otherwise specified, deliveries shall be made to the Delivery Point specified above Mondays through Fridays (excluding Federal Holidays) between the hours of 8:30 a.m. and 5:30 p.m. EST only. Supplies or services scheduled for delivery on a Federal holiday shall be made the following day.

### ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

#### FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

**52.242-15, Stop Work Order** (August 1989) with **Alternate I** (April 1984).



## **SECTION G - CONTRACT ADMINISTRATION DATA**

Any contract awarded from this RFP will contain the following:

### **ARTICLE G.1. PROJECT OFFICER**

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

### **ARTICLE G.2. KEY PERSONNEL**

Pursuant to the Key Personnel clause incorporated in this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

NAME

TITLE

[To be specified prior to award]]

### **ARTICLE G.3. WORK ASSIGNMENT PROCEDURES**

In providing support under this contract, the Contractor shall initiate work only when so directed by a Work Assignment (Attachment provided in Section J.). Approval of a Work Assignment shall not constitute approval to exceed any item listed in the contract or general clauses of the contract. Work Assignment amounts shall not exceed the total amounts listed in the contract (time, dollars, effort, consultants, travel, etc.). The Project Officer with Contracting Officer approval, is authorized to initiate Work Assignments and to sign Work Assignments indicating satisfactory performance/delivery of the services/product required in each Work Assignment. The Contractor shall assure, prior to commencing work on any Work Assignment, that written approval of the Project Officer and the Contracting Officer has been obtained. A Work Assignment which does not contain both Contracting Officer and Project Officer approval signatures shall be considered invalid and costs incurred for such work shall be considered unallowable. The Contractor shall not exceed the estimated labor hours, estimated Work Assignment amount, or change the Work Assignment leader without prior written approval of the Project Officer and the Contracting Officer by modification of the Work Assignment. The day-to-day operational and administrative details of the Work Assignment system will be established by the Project Officer with input from the Contractor. The Work Assignment system will operate within the following general guidelines:

a. Work Assignment (W.A.) Information

- (1) All work to be assigned under this contract shall relate directly to one or more of the task areas listed in the statement of work.
- (2) Each W.A. shall be written for the conduct of a specific, finite task.
- (3) Each new W.A. shall be numbered serially beginning with 01.
- (4) Each W.A. shall be completed on the form entitled "NCI Contract Work Assignment" and listed as an Attachment in Section J of this contract.
- (5) Upon award of the contract, an Administrative Work Assignment, as shown in SECTION J, Attachments, shall be issued on a yearly basis. This Work Assignment will cover the time and expenditures necessary for the administration of the contract.

b. Initiation of a W.A.

- (1) The Project Officer will initiate Part I of the W.A.
- (2) The Contractor shall complete Part II and obtain the appropriate signature. The Contractor shall forward the proposed W.A. to the Project Officer.
- (3) Upon receipt of the proposed W.A. and after determining that the proposed W.A. is acceptable, the Project Officer will sign Part II to indicate recommendation for approval and forward to the Contracting Officer.
- (4) Upon receipt, the Contracting Officer will review the proposed W.A.
  - (a) If approved, the Contracting Officer will sign Part II to indicate approval and will forward the W.A. to the Contractor with a copy to the Project Officer.
  - (b) If not approved, the Contracting Officer will notify the Project Officer, stating the reasons for disapproval.
- (5) After receipt of the approved W.A., the Contractor shall begin work. The period of performance shall never precede the Contracting Officer Approval date.

c. Modification to a W.A.

- (1) Each amendment to an existing work assignment shall contain the original W.A. number and shall designate a modification number. Modification numbers for each W.A. shall be serially numbered beginning with 01 (for example, Work Assignment 01, Modification No. 01).
- (2) Each W.A. modification shall set forth in specific detail which portion(s) of the W.A. is to be modified. All Cost/Labor modifications shall be in the following format:

	Authorized to Date	This Modification	Revised Estimate
Labor Hours			
Cost Elements (List Each Element)			

d. Conclusion of a W.A.

- (1) For each W.A. performed, the Contractor shall prepare PART III of the W.A. for submission to the Contracting Officer.
- (2) This PART III submission shall include all actual information (cost, effort, and deliverables) relative to the W.A.
- (3) PART III of the W.A. shall be submitted as soon as possible and not to exceed three months after the closing date of the W.A. For those Work Assignments which expire within three months prior to the contract expiration date, PART III of the Work Assignment shall be submitted on the final contract day.
- (4) After verification that all work is complete and deliverables have been received and accepted, the Project Officer will sign Part III of the W.A. to indicate recommendation for approval and forward the W.A. to the Contracting Officer.
- (5) After verification that the W.A. has been satisfactorily completed, the Contracting Officer will approve completion of the W.A. by signing Part III of the W.A. and forward to the Contractor.

**ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT**

- a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

- (1) Invoices/financing requests shall be submitted as follows:

- (a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN261200411000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N02-CM-41234.)

- (b) An original and two copies to the following designated billing office:

Contracting Officer  
Office of Acquisitions  
National Cancer Institute, NIH  
EPS, Room 6001  
6120 EXECUTIVE BLVD MSC 7193  
BETHESDA MD 20892-7193

- (2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301)496-8620.

## **ARTICLE G.5. INDIRECT COST RATES**

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7(d)(2), "Allowable Cost and Payment" incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services  
Office of Contracts Management  
National Institutes of Health  
6100 Building, Room 6B05  
6100 EXECUTIVE BLVD MSC 7540  
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

## **ARTICLE G.6 . POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

### **a. Contractor Performance Evaluations**

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

### **b. Electronic Access to Contractor Performance Evaluations**

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

<http://oamp.od.nih.gov/OD/CPS/cps.asp>

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

## **SECTION H - SPECIAL CONTRACT REQUIREMENTS**

### **ARTICLE H.1. HUMAN SUBJECTS**

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

## **ARTICLE H.2. NEEDLE EXCHANGE**

- a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b.     **Public Law and Section No.**                      **Fiscal Year**                      **Period Covered**

[Applicable information to be included at award]

## **ARTICLE H.3. OMB CLEARANCE**

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

## **ARTICLE H.4. OPTION PROVISION**

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of Years 1 through 5 of the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-8 set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform Years 1 through 5 of the Statement of Work as also defined in Sections C and F of this contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in Article B.3.

## **ARTICLE H.5. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL**

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

## **ARTICLE H.6. CONFIDENTIALITY OF INFORMATION**

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (MARCH 2005):

## **ARTICLE H.7. PUBLICATION AND PUBLICITY**

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. (to be determined).

## ARTICLE H.8. PRESS RELEASES

- a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b.	Public Law and Section No.	Fiscal Year	Period Covered
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[Applicable information to be included at award]

## ARTICLE H.9. ANTI-LOBBYING

- a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.
- b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c.	Public Law and Section No.	Fiscal Year	Period Covered
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[Applicable information to be included at award]

## ARTICLE H.10. INTELLECTUAL PROPERTY OPTION TO COLLABORATOR

NCI may collaborate with an outside investigator who has proprietary rights to compounds which may be assigned under this contract. This collaborator will be identified by the Project Officer (PO) at the time of assignment and in this case, the following option regarding Intellectual Property Rights will be applicable.

Contractor agrees to promptly notify the NCI and "Collaborator" in writing of any inventions, discoveries or innovations made by the contractor's principal investigator or any other employees or agents of the contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of this study using Collaborator's Study Agent (hereinafter "Contractor Inventions").

Contractor agrees to grant to Collaborator: (1) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (2) a time-limited first option to negotiate an exclusive world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Contractor Inventions on terms to be negotiated in good faith by Collaborator and Contractor. Collaborator shall notify Contractor, in writing, of its interest in obtaining an exclusive license to any Contractor Invention within six (6) months of Collaborator's receipt of notice of such Contractor Invention(s). In the event that Collaborator fails to so notify Contractor or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Contractor Invention, and Contractor will be free to dispose of its interests in such Contractor Invention in accordance with its own policies. If Contractor and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter, Contractor shall not offer to license the Contractor Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator shall have a period of thirty (30) days in which to accept or reject the offer.

Contractor agrees that notwithstanding anything herein to the contrary, any inventions, discoveries or innovations, whether patentable or not, which are not Subject Inventions as defined in 35 U.S.C. 201(e),\* arising out of any

unauthorized use of the Collaborator's Study Agent shall be the property of the Collaborator (hereinafter "Collaborator Inventions"). Contractor will promptly notify the Collaborator in writing of any such Collaborator Inventions and, at Collaborator's request and expense, Contractor will cause to be assigned to Collaborator all right, title and interest in an to any such Collaborator Inventions and provide Collaborator with reasonable assistance to obtain patents (including causing the execution of any invention assignment or other documents). Contractor may also be conducting other more basic research using Study Agent under the authority of a separate Material Transfer Agreement (MTA), or other such agreement with the Collaborator. Inventions arising thereunder shall be subject to the terms of the MTA, and not to this clause.

\*35 U.S.C. (e): The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d)(FOOTNOTE 1) of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

#### **Protection of Proprietary Data**

Data generated using an investigational agent proprietary to a Collaborator will be kept confidential and shared only with the NCI and the Collaborator. The Contractor retains the right to publish research results subject to the terms of this contract.

#### **ARTICLE H.11. CONSTITUTION DAY**

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

## PART II - CONTRACT CLAUSES

### SECTION I - CONTRACT CLAUSES

THE FOLLOWING **ARTICLE I.1 GENERAL CLAUSE LISTING(S)** WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

#### **General Clauses for a Cost-Reimbursement Service Contract**

The complete listing of these clauses may be accessed at:

<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clauses.jsp>

#### **ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES**

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

FAR Clause **52.249-4, Termination For Convenience Of The Government (Services) (Short Form)** (April 1984), is deleted in its entirety and FAR Clause **52.249-2, Termination For Convenience Of The Government (Fixed Price)** (September 1996) is substituted therefor.

#### **ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES**

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

##### **a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES**

(1) FAR Clause **52.216-4, Economic Price Adjustment - Labor and Material** (January 1997).

(2) FAR Clause **52.217-8, Option to Extend Services** (November 1999).

"...The Contracting Officer may exercise the option by written notice to the Contractor within [INSERT THE PERIOD OF TIME WITHIN WHICH THE CONTRACTING OFFICER MAY EXERCISE THE OPTION].

(3) FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

(4) FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).



(5) FAR Clause **52.227-14, Rights in Data - General** (June 1987).

(6) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

(7) FAR Clause **52.248-1, Value Engineering** (February 2000).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

(1) HHSAR Clause **352.223-70, Safety and Health** (January 2001). [This clause is provided in full text in Section J - Attachments.]

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

(1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984) (OMB Bulletin 81-16).

**ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT**

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)

(a) Definition. As used in this clause--

*United States* means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to

collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board  
Division of Information  
1099 14th Street, N.W.  
Washington, DC 20570  
1-866-667-6572  
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at <http://www.nlr.gov>.

- (c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.
- (d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.
- (e) The requirement to post the employee notice in paragraph (b) does not apply to--
  - (1) Contractors and subcontractors that employ fewer than 15 persons;
  - (2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;
  - (3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;
  - (4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--
    - (i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
    - (ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or
  - (5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.
- (f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--
  - (1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

- (2) Download a copy of the poster from the Office of Labor-Management Standards website at <http://www.olms.dol.gov>; or
  - (3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.
- (g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

#### SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	<a href="http://rcb.cancer.gov/rcb-internet/forms/intent.jsp">http://rcb.cancer.gov/rcb-internet/forms/intent.jsp</a>
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP

**TECHNICAL PROPOSAL ATTACHMENTS:** (The following attachments must be completed, where applicable, and submitted with the Technical Proposal.)

Attachment No.	Title	Location
Attachment 6:	Technical Proposal Cost Summary	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 7:	Summary of Related Activities	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>

**BUSINESS PROPOSAL ATTACHMENTS:** (The following attachments must be completed, where applicable, and submitted with the Business Proposal.)

Attachment No.	Title	Location
Attachment 11:	Proposal Summary and Data Record, NIH-2043	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 13:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a> <a href="http://ocm.od.nih.gov/contracts/sps/spshecl.xls">http://ocm.od.nih.gov/contracts/sps/spshecl.xls</a>
Attachment 14:	Offeror's Points of Contact	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 15:	Certificate of Current Cost or Pricing Data	<a href="http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf">http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf</a>
Attachment 17:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://rcb.cancer.gov/rcb-internet/forms/sfillin.pdf">http://rcb.cancer.gov/rcb-internet/forms/sfillin.pdf</a>

**INFORMATIONAL ATTACHMENTS:** (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance.)

Attachment No.	Title	Location
Attachment 18:	Sample Work Assignment	<a href="http://rcb.cancer.gov/rcb-internet/forms/wkassign.pdf">http://rcb.cancer.gov/rcb-internet/forms/wkassign.pdf</a>

Attachment 22:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	<a href="http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf">http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf</a>
Attachment 23:	Financial Report of Individual Project/Contract, NIH 2706	<a href="http://www.niaid.nih.gov/contract/forms/nih-2706.pdf">http://www.niaid.nih.gov/contract/forms/nih-2706.pdf</a>
Attachment 24:	Instructions for Completing Form NIH 2706	<a href="http://www.niaid.nih.gov/contract/forms/instructions2706.pdf">http://www.niaid.nih.gov/contract/forms/instructions2706.pdf</a>
Attachment 26:	Safety and Health, HHSAR Clause 352.223-70	<a href="http://www.niaid.nih.gov/contract/forms/form10.pdf">http://www.niaid.nih.gov/contract/forms/form10.pdf</a>
Attachment 27:	Procurement of Certain Equipment, NIH(RC)-7	<a href="http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf">http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf</a>
Attachment 31:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf">http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf</a>

## PART IV - REPRESENTATIONS AND INSTRUCTIONS

### **SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

SECTION K can be accessed electronically from the INTERNET at the following address:

<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

**IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.**

## SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

### 1. GENERAL INFORMATION

#### a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2004)]

(a) *Definitions.* As used in this provision--

*Discussions* are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

*"In writing", "writing", or "written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

*"Proposal modification"* is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

*"Proposal revision"* is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

*"Time,"* if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.* (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

- (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines

that accepting the late offer would not unduly delay the acquisition; and--

- (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
    - (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
    - (3) It is the only proposal received.
  - (B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.
- (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
  - (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
  - (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
  - (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
  - (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
  - (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
  - (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).
  - (e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be



disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

- (2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."
  - (3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.
- (f) *Contract award.* (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
- (2) The Government may reject any or all proposals if such action is in the Government's interest.
  - (3) The Government may waive informalities and minor irregularities in proposals received.
  - (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest

number that will permit an efficient competition among the most highly rated proposals.

- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:
  - (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
  - (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
  - (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
  - (iv) A summary of the rationale for award.
  - (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
  - (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

**Alternate I** (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

- (f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

**b. NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications

(See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

- (1) The North American Industry Classification System (NAICS) code for this acquisition is 541940.
- (2) The small business size standard is 750 employees.

**THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.**

**c. TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that Multiple Awards will be made from this solicitation and that the awards will be made on/about September 29, 2006.

It is anticipated that the awards from this solicitation will be a multiple-year, cost reimbursement type contract completion with a term of 5 years with 2 option years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

**d. ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 9600 labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

**e. COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

**f. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

**g. RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

**h. COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other

factors considered.

i. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

j. **SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2**

- (a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer  
Office of Acquisitions  
National Cancer Institute  
EPS, Room 6052  
6120 EXECUTIVE BLVD MSC-7193  
BETHESDA MD 20892-7193

- (b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

## **2. INSTRUCTIONS TO OFFERORS**

### **a. GENERAL INSTRUCTIONS**

#### **INTRODUCTION**

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

#### **(1) Contract Type and General Clauses**

It is contemplated that a [cost-reimbursement (completion/level of effort)/fixed-price] type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

#### **(2) Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

##### **I. COVER PAGE**

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

##### **II. TECHNICAL PROPOSAL**

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

##### **III. BUSINESS PROPOSAL**

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

#### **(3) Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD.)

#### **(4) Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY). However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or

amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

**Hard Metric** - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

**Soft Metric** - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

**Dual Systems** - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

#### **(10) Selection of Offerors**

- a) The acceptability of the [scientific and] technical portion of each [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-

- (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

- (2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects

of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- f) The NCI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

#### **(11) ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented ) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

#### **(12) Past Performance Information**

- a) Offerors shall submit the following information as part of their [business/technical] proposal.

A list of the last        contracts completed during the past [one/two/three] years and [all contracts/the last        contracts awarded] currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort.



The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

**(13) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
- b) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
- c) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- d) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
- e) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- f) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

## **b. TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

### **(1) Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

#### **(a) Statement of Work**

##### **(1) Objectives**

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

##### **(2) Approach**

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

##### **(3) Methods**

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

##### **(4) Schedule**

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

#### **(b) Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

**OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR**

**MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.**

**(1) Principal Investigator/Project Director**

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

**(2) Other Investigators**

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

**(3) Additional Personnel**

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

**(4) Resumes**

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

**(2) Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Section M.3., hereof).

**(3) Additional Technical Proposal Information**

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

#### (4) Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.
- e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

#### (5) Special Proposal Instructions Specific to this RFP:

##### **Mandatory Qualification Criteria**

- A. Offeror must have the necessary licenses required by the Local, State and Federal governments to handle, synthesize, store and ship such compounds, and dispose of toxic waste.

##### **Justification**

As many of the compounds assigned for resynthesis may be of hazardous nature, the Offeror must have the necessary licenses required by the Local, State and Federal governments to handle, synthesize, store and ship such compounds. The Offerors are expected to be in compliance with Environmental Protection Agency regulations regarding the discharge of water and air pollutants and for assuring that disposal of all chemical residues meet current EPA regulations.

##### **Mandatory Exclusion**

- B. The resynthesis program is vital to the DTP drug discovery and development program. The compounds assigned for resynthesis are some times those procured by the NCI under the terms of confidentiality agreements. The Offeror, therefore, cannot be one with proprietary commercial interest in the pharmaceutical, chemical or biotechnology area. Therefore both large and small business commercial pharmaceutical, chemical and biotechnology firms and their subsidiaries are excluded from competing for this contract.

##### **Justification**

The NCI often signs legally binding agreements with some suppliers (often pharmaceutical or chemical companies) and principle investigators of all projects under development, which state that all information on compounds donated by those suppliers will be held confidential. The occasion may arise whereby the successful Offeror will be assigned such a confidential compound for a synthesis or sometimes modification of the parent molecule. If the Offeror were a chemical or pharmaceutical company they could gain valuable data on confidential new lead compounds. The NCI believes that in order to honor the confidentiality agreement with suppliers and in order to avoid any chance of transmitting privileged data to a competitor, pharmaceutical and chemical companies and their subsidiaries must be excluded from the competition. A pharmaceutical or chemical company is defined as an organization which sells drugs and/or chemicals to the general public for profit.

c. **BUSINESS PROPOSAL INSTRUCTIONS**

(1) **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) **Cost and Pricing Data**

1. **General Instructions**

A. You must provide the following information on the first page of your pricing proposal:

- (1) Solicitation, contract, and/or modification number;
- (2) Name and address of offeror;
- (3) Name and telephone number of point of contact;
- (4) Name of contract administration office (if available);
- (5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
- (6) Proposed cost; profit or fee; and total;
- (7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
- (8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
- (9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
- (10) Date of submission; and
- (11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

- (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
  - (2) The nature and amount of any contingencies included in the proposed price.
- D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
- E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
- F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
- G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
- H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

## 2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

- A. **Materials and services.** Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.
- (1) *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).
  - (2) *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime

contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

- B. **Direct Labor.** Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. **Indirect Costs.** Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. **Other Costs.** List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. **Royalties.** If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:
  - (1) Name and address of licensor.
  - (2) Date of license agreement.
  - (3) Patent numbers.
  - (4) Patent application serial numbers, or other basis on which the royalty is payable.
  - (5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
  - (6) Percentage or dollar rate of royalty per unit.
  - (7) Unit price of contract item.
  - (8) Number of units.
  - (9) Total dollar amount of royalties.
  - (10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).
- F. **Facilities Capital Cost of Money.** When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

### 3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

- 4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price

proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

***[NOTE: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.]***

(3) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

(4) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$500,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at:

<http://www.sba.gov/size>

The Department of Commerce website for the annual determination for NAICS codes\* is:

<http://www.arnet.gov/References/sdbadjustments.htm>.

*\*Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**



If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

#### EXAMPLE

##### Targets for SDB Participation - NAICS Subsector 223

	<b>SDB Percentage of Total Contract Value</b>	<b>SDB Dollars</b>
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime  (Includes joint venture partners and team arrangements)*	10%	\$100,000
SDB Participation by subcontractors	15%	\$150,000

\*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

#### (5) **Total Compensation Plan - Instructions**

- a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors [included in the competitive range will be required to/as a part of their business proposal] will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
- b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
- c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted

by each offeror.

(6) **Total Compensation Plan - Evaluation**

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(7) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

*General experience* is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

*Organizational experience* is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

*Performance history* is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

*Pertinent contracts* is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(8) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

- (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
- (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

c) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38, (May 1999)**

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission

satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

- (1) The solicitation number (or other procurement identification number).
- (2) The offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

**HHSAR 352.232-75, Incremental Funding (January 2001)**

- (a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.
- (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

f) **Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)**

(This is applicable if you are a commercial organization.)

- (a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if

the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

- (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

- ☐ The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).
- ☐ The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(9) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a) Willingness to perform as a subcontractor for specific duties (list duties).
- b) What priority the work will be given and how it will relate to other work.
- c) The amount of time and facilities available to this project.
- d) Information on their cognizant field audit offices.
- e) How rights to publications and patents are to be handled.
- f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

(10) **Proposer's Annual Financial Report**

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(11) **Representations and Certifications**

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(12) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

## SECTION M - EVALUATION FACTORS FOR AWARD

### 1. General

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that Offeror whose proposal provides the best overall value to the Government.

The technical proposal will receive paramount consideration in the selection of the Offeror for this procurement. In the event that the technical evaluation reveals that two or more Offerors are approximately equal in technical ability, then the cost may become a significant factor in determining award(s). In any event, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

The evaluation will be based on the demonstrated capabilities of the prospective Offerors in relation to the needs of the project as set forth in the Request for Proposal (RFP). The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the Statement of Work. *Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work, will not be eligible for the award.* The Offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving those objectives. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below. Listed below are mandatory qualification criteria and technical evaluation criteria. The qualification criteria establish conditions which *must be met* at the time of initial proposal submission. The evaluation criteria will be used by the technical evaluation committee when reviewing the technical proposals.

### 2. Mandatory Qualification Criteria

Listed below are mandatory qualification criteria. The qualification criteria establish conditions which ***must be met at the time of initial proposal submission*** and will be reviewed by the Contracting Officer prior to considering your proposal for evaluation or award.

- A. Offeror must have the necessary licenses required by the Local, State and Federal governments to handle, synthesize, store and ship such compounds, and dispose of toxic waste.

#### Justification

As many of the compounds assigned for resynthesis may be of hazardous nature, the Offeror must have the necessary licenses required by the Local, State and Federal governments to handle, synthesize, store and ship such compounds. The Offerors are expected to be in compliance with Environmental Protection Agency regulations regarding the discharge of water and air pollutants and for assuring that disposal of all chemical residues meet current EPA regulations.

#### Mandatory Exclusion

- B. **The resynthesis program is vital to the DTP drug discovery and development program. The compounds assigned for resynthesis are some times those procured by the NCI under the terms of confidentiality agreements. The Offeror, therefore, cannot be one with proprietary commercial interest in the pharmaceutical, chemical or biotechnology area. Therefore both large and small business commercial pharmaceutical, chemical and biotechnology firms and their subsidiaries are excluded from competing for this contract**

#### Justification

The NCI often signs legally binding agreements with some suppliers (often pharmaceutical or chemical companies) and principle investigators of all projects under development, which state that all information on compounds donated

by those suppliers will be held confidential. The occasion may arise whereby the successful Offeror will be assigned such a confidential compound for a synthesis or sometimes modification of the parent molecule. If the Offeror were a chemical or pharmaceutical company they could gain valuable data on confidential new lead compounds. The NCI believes that in order to honor the confidentiality agreement with suppliers and in order to avoid any chance of transmitting privileged data to a competitor, pharmaceutical and chemical companies and their subsidiaries must be excluded from the competition. A pharmaceutical or chemical company is defined as an organization which sells drugs and/or chemicals to the general public for profit.

### 3. Technical Evaluation Criteria

The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes. Proposals submitted in response to this Request for Proposal will be evaluated in accordance with the following factors:

	<u>Weight</u>
a. <u>Personnel</u>	<b>40%</b>
(1) Relevance and quality of the Principal Investigator's recent experience and accomplishments in organic synthesis, qualifications for leading this project, and availability for assignment.	
(2) Relevance and extent of experience of the other investigators, based on recent examples of pertinent accomplishments in organic syntheses.	
(3) Availability of the proposed team and evidence of functioning as a team.	
b. <u>Technical Approach</u>	<b>25%</b>
(1) Practicality of synthetic methodology proposed for the three examples as reflected by the description of the synthesis and suitability of relevant citations and examples from the literature.	
(2) Adequacy of proposed purification and characterization of key intermediates and target compounds.	
c. <u>Facilities and Equipment</u>	<b>25%</b>
(1) Suitability and availability of appropriate facilities including laboratory space and equipment.	



- (2) Availability of essential equipment required for organic synthesis, analytical instruments, and spectroscopic equipment. (HPLC, IR, UV, NMR, MS)
- (3) Availability of library resources including on-line search capability.

d. Organizational Experience and Capability **10%**

- (1) Pertinent background experience and qualifications of organization.
- (2) Evidence of organizational support.
- (3) Adequacy of the safety procedures for ensuring the safety of the personnel on this project.

\_\_\_\_\_  
**Total** **100%**

**4. Past Performance Factor**

The Offeror's past performance will be evaluated after determination of the competitive range. Only those Offerors included in the competitive range will be evaluated. The Government will evaluate the quality of the Offeror's past performance based on information obtained from references provided by the Offeror, as well as other relevant past performance information obtained from other sources known to the Government.

Evaluation of past performance will be a subjective assessment based on a consideration of all relevant facts and circumstances. It will not be based on absolute standards of acceptable performance. The Government is seeking to determine whether the Offeror has consistently demonstrated a commitment to customer satisfaction and timely delivery of services at fair and reasonable prices.

The assessment of the Offeror's past performance will be used as a means of evaluating the relative capability of the Offeror and the other competitors. Thus, an Offeror with an exceptional record of past performance may receive a more favorable evaluation than another whose record is acceptable, even though both may have acceptable technical proposals. Past performance will not be scored, but the Government's conclusions about overall quality of the Offeror's past performance will be highly influential in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered most advantageous to the Government.

By past performance, the Government means the Offeror's record of conforming to specifications and to standards of good workmanship; the Offeror's record of forecasting and controlling costs; the Offeror's adherence to contract schedules, including the administrative aspects of performance; the Offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the Offeror's business-like concern for the interest of the customer.

The Government will consider the number or severity of an Offeror's problems, the effectiveness of corrective actions taken, the Offeror's overall work record, and the age and relevance of past performance information.

The lack of a performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror.

**5. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the Offeror's SDB Participation targets will be used in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered to offer the best value to the Government.

The extent of the Offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the Offeror's proposal. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offerors will be evaluated on the following sub-factors:

1. The extent to which SDB concerns are specifically identified;
2. The extent of commitment to use SDB concerns;
3. The complexity and variety of the work SDB concerns are to perform;
4. The realism of the proposal;
5. Past performance of offerors in complying with subcontracting plan goals for SDB participation; and
6. The extent of participation of SDB concerns in terms of value of the total acquisition.

## **6. EVALUATION OF OPTIONS**

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options. (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

## **7. ADDITIONAL TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

A detailed work plan must be submitted indicating how each aspect of the Statement of Work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

Offerors must include a separate section, tabbed with page numbers (preferred in binders, no clips) of the Technical Proposal a discussion of how they meet the Mandatory Qualification Criteria required by Section M.2. Mandatory Qualification Criteria.

### **1. Technical Discussions**

The technical discussions included in the technical proposal should respond to the items set forth below:

#### **A. Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the work group, its general qualifications, and recent experience with similar programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the percentage of their total time each will be available for this program. For all proposed personnel who are not currently members of the Offeror's staff, state the qualifications to be sought and provide resumes of persons under consideration if available. Letters of commitment are required for all proposed staff who are not currently employed by the proposing organization.

Offerors should assure that the Principal Investigator, and all other personnel proposed, shall not be committed on Federal grants and contracts for more than a total of 100% of their time. If the situation arises where it is determined that a proposed employee is committed for more than 100% of his or her time, the Government will require action on the part of the Offeror to correct the time commitment.

1. Principal Investigator

The Principal Investigator shall be responsible for the overall implementation of the contract and shall be the institution's key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, recent experience in chemical synthesis, and recent examples of successfully completed chemical syntheses by the Principal Investigator. State the estimated time to be spent on the project and the areas for which he/she will be responsible. (It is desirable that the Principal Investigator be assigned to this project a minimum of 10-15% of the time).

Frequent communications between the NCI Project Officer and the Contractors are essential to maintain the effectiveness of the contracts to address and remedy problems of synthesis and those arising from changes in the biological evaluation procedures and priorities which may impact the operations of the contract.

2. Other Investigators

List all other investigators/professional personnel who will be participating in the project. All other technical support personnel should be trained chemists, at least at the B.S. level or above. It is desirable that other investigator(s) devote at least 50%, and preferably 100%, of their time to this project. Discuss their qualifications, experience, and accomplishments in the area of chemical synthesis, giving examples. State the estimated time each will spend on the project and the areas or phases for which each will be responsible.

3. Additional Personnel

List names and titles of additional personnel, if any, who will be required for full-time employment, or on a consultant basis.

4. Consultants/Subcontractors

If subcontractors or consultants are proposed, the following information must be included in your proposal:

- a. Detailed justification of the need for consultants or subcontractors.
- b. A statement from the consultant(s) or subcontractor(s) detailing:
  - (1) The specific items or expertise they will provide.
  - (2) Their availability to the project and the amount of time anticipated.
  - (3) Willingness to act as a consultant or a subcontractor.
  - (4) How confidentiality of discreet compounds, rights to publications and patents will be handled.
- c. A consultant or a subcontractor may not serve as the Principal Investigator.

5. Resumes

Updated resumes of the Principal Investigator and of all other professional personnel assigned to this project should be provided, including those for consultants or subcontractors. Each should indicate educational background, recent experience related to chemical synthesis, and other related scientific or technical accomplishments. Designate those publications directly related to this proposal for each of the investigators named. Unrelated data or resumes of individuals not assigned to or involved with the proposed work group are neither necessary nor desired.

B. Technical Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss how you would proceed with the preparation of the three compounds listed below (Figure 3) as examples. Include literature examples where available and if more than one synthesis is available justify your choice of approach. Discuss problems you might encounter and give your proposed solutions to such problems. Discuss your proposed solutions to such problems.

**Describe in detail the approaches that you would use for synthesis, purification and characterization of each of the examples 1, 2 and 3 shown in *Figure 3* (attached). Indicate the time required for completion of each synthesis and cost for each on a 100 mg and 100gm basis. Also discuss in detail any change in the procedure you may propose to improve existing synthesis to prepare larger amounts.**

**Note that the compounds cited above are only examples for the purpose of demonstrating your capabilities for this project and are not the compounds you will be asked to actually prepare or modify.**

C. Facilities and Equipment

Describe in detail the laboratory space to be used for this project. In situations where more than one building or institution is involved, a clear description shall be given of the location of all sites, distance and travel time between them. While it is expected that most of the equipment is dedicated and will be under the direct control of the Principal Investigator, special mention shall be made when this is not the case.

When equipment is only available on a shared basis evidence shall be provided as to who is responsible for controlling access and how determination of priority of usage will be made (letter of commitment from department head, etc.).

1. Each Contractor shall have available a fully operational facility, including all necessary equipment for organic and inorganic synthesis. Provide floor plans with dimensions and describe location and relationships of facilities directly involved. Indicate the extent of dedication to this project.
2. The offeror shall have immediate and preferably hands-on access to the following equipment: infrared spectrometer, UV-VIS spectrometer, low field proton NMR, and analytical HPLC. Ready availability of preparative scale HPLC will be helpful. List available equipment, including brand names and model numbers; proximity to the project work area; and provisions for access to team members.
3. The Contractor should have available on short turnaround high resolution mass spectroscopy and high field proton and  $^{13}\text{C}$  NMR service capable of providing multiple irradiation data. Combustion analysis may be available in-house or from a commercial laboratory. Describe equipment in this category available to you including the location of equipment, arrangements for obtaining such data in the form of a letter of commitment from the provider and the expected turnaround time.
4. Describe the library resources available to you. Note the extent of the collection of major chemical journals and the accessibility to computer on-line literature search capability. Describe the proximity of the library to the project work area.

D. Organization's Capability and Experience

Describe the organization's experience in supporting synthetic organic chemistry groups. The relationship of the proposed project team within the offeror's organizational structure shall be explained, as well as how this relationship will facilitate the proposed work. Provide an organizational chart showing lines of responsibility and authority as they relate to this project. Review pertinent work performed by your organization which is relevant to this project and your proposed approach. Please note that organizational experience is defined as the accomplishment of work, either past or ongoing, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

Substances under study shall be considered to be toxic agents and, thus, shall be handled accordingly. The Contractor shall comply with all pertinent local, state and federal government safety regulations such as those required by the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA). Describe the organization's general safety program in case of fire, acid spills, explosions, etc., as well as your proposed approach for the handling of toxic agents, and the protection of laboratory personnel. Provide two copies of your organization's safety manual.

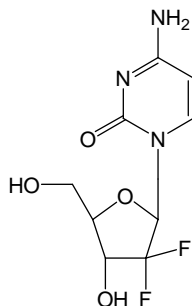
E. Supplies

For proposal purposes, direct materials, supplies, analyses and cost of packaging and distribution of the materials for this project should be estimated at \$50,000 per year per contract.

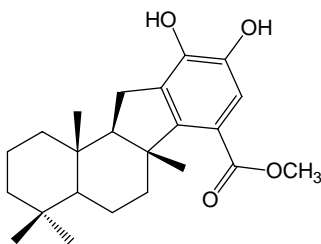
F. Travel

No travel anticipated.

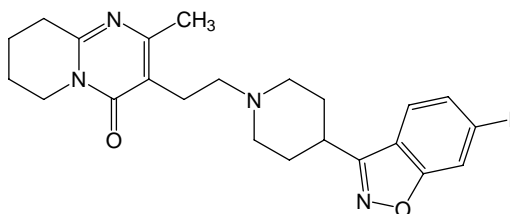
Figure 3



Example 1, (Gemcitabine)



Example 2, Pelorol



Example 3, Risperidone

Describe in detail the approaches that you would use for synthesis, purification and characterization of each of the examples 1, 2 and 3 shown in *Figure 3* (attached). Indicate the time required for completion of each synthesis and cost for each on a 100 mg and 100gm basis. Also discuss in detail any change in the procedure you may propose to improve existing synthesis to prepare larger amounts.

Note that the compounds cited above are only examples for the purpose of demonstrating your capabilities for this project and are not the compounds you will be asked to actually prepare or modify.

## **SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP**

The following pages include Attachments applicable to this RFP as specified in SECTION J - List of Attachments

## PACKAGING AND DELIVERY OF THE PROPOSAL

Your proposal shall be organized as specified in Section L.2., "Instructions to Offerors" - General Instructions. Shipment and marking shall be as indicated below.

### EXTERNAL PACKAGE MARKING

In addition to the address cited below, mark each package as follows:

**"RFP NO. N02-CM-57030-45**

**TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"**

### **PLEASE READ THE FOLLOWING INFORMATION CAREFULLY:**

#### NUMBER OF COPIES

TECHNICAL PROPOSAL: **ORIGINAL\* AND 10 COPIES TO:**

BUSINESS PROPOSAL: **ORIGINAL\* AND 10 COPIES TO:**

#### If hand-delivered or delivery service

Kathleen E. Giuliano  
Contract Specialist  
Office of Acquisitions  
National Cancer Institute  
Executive Plaza South, Room 6052  
6120 Executive Boulevard  
Rockville, Maryland 20852

#### If using U.S. Postal Service

Kathleen E. Giuliano  
Contract Specialist  
Office of Acquisitions  
National Cancer Institute  
Executive Plaza South, Room 6052  
6120 EXECUTIVE BLVD MSC-7193  
BETHESDA MD 20892-7193

\*THE ORIGINALS MUST BE READILY ACCESSIBLE FOR DATE STAMPING PURPOSES.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the Rockville, Maryland address. Any package sent to the Rockville address via this service will be held at a local post office for pick-up. The Government is not responsible for picking up any mail at a local post office. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal."



**STATEMENT OF WORK****Synthesis of Non-GMP Small Molecules****STATEMENT OF WORK****A. BACKGROUND OBJECTIVES**

The Drug Synthesis and Chemistry Branch (DS&CB) of the Developmental Therapeutics Program (DTP) of the Division of Cancer Treatment and Diagnosis (DCTD) of the National Cancer Institute (NCI) has the responsibility for the acquisition of organic and inorganic chemical compounds as potential antitumor agents which can be used in the NCI Rapid Access to Intervention Development Program (RAID) and Rapid Access to NCI Discovery Resources (R\*A\*N\*D) programs, and Exploratory IND Studies "Phase 0" clinical trials, and other NCI/NIH programs. The Government is seeking Contractors with established expertise in the field of synthesis of organic and inorganic compounds to prepare those deemed of interest to the program for evaluation as antitumor agents.

This project will support the program objectives of DS&CB by accomplishing the following specific objectives:

1. Synthesize samples of compounds which have been designated of interest to the DTP drug development program and which are not available from the original sources.  
Compounds will also be required for either primary screening, follow-up testing or pharmacology studies. These compounds may be used in the Exploratory IND Studies or "Phase 0" clinical trials.

<http://www.fda.gov/>

<http://www.fda.gov/cder/guidance/7086fml.pdf>

- a. Compounds assigned for synthesis will be primarily potential antitumor agents and include, but not be limited to, carbocycles, heterocycles typically containing nitrogen, oxygen, and sulfur, carbohydrates, nucleosides and metal coordination complexes.
  - b. Amounts of compounds to be synthesized will vary widely but will usually be in the range from 100 mg to 100 gram.
2. Synthesize chemical compounds of high purity as identified by DS&CB.
3. Confirm structure and determine selected physical and/or chemical data on compounds (i.e., solubilities, stability, etc.) which will be used to help determine testing, formulation and storage conditions.

**B. WORK ASSIGNMENTS**

Work Assignments for syntheses will be issued under a cost-reimbursement, completion type contract resulting from this solicitation. Work Assignments will be initiated by the Project Officer, who will forward a request to the Principal Investigator stating the period of performance, the specific work to be performed, and the deliverables.

The Contractor will submit to the Project Officer a detailed description of the technical approach to be used in carrying out the Work Assignment, and an estimate of the required effort and cost for the specified period. The level of effort (hours) and cost of a Work Assignment shall not exceed the funds remaining in an incrementally-funded period. With the concurrence of the Project Officer, the Contracting Officer will then execute the Work Assignment. Soon after completion of each technical task, the Contractor shall deliver the compounds, the required data sheets and the detailed preparative procedures to the Project Officer. No later than two months after completion of the Work Assignment, the Contractor will forward to the Project Officer a Work Assignment Completion Report providing a listing of the actual labor and cost for the Work Assignment and the stated deliverables. Upon the recommendation of the Project Officer, the Contracting Officer will then approve the Work Assignment for completion.

Subsequent to the award of the contracts, an Administrative Work Assignment shall be issued on a yearly basis. The Work Assignment will cover the time and expenditures necessary for administration of the contract. As shown in Section J, Attachment H (18), the Work Assignments specifically applicable to this Administrative Work Assignment will consist of and be limited to: (1) preparation of responses to subsequent Work Assignments; (2) preparation of final Work Assignment Reports, Annual Reports, and the Final Contract Report; (3) allowable travel expenditures. In addition, the Administrative Work Assignment shall include the costs of storage, analysis and shipment of materials.

## **C. STATEMENT OF WORK**

### **1. Resynthesis Requirement**

The Contractor shall synthesize, purify, characterize, and submit to the DS&CB target compounds of high purities, and small libraries of analogs of lead compounds (4-8 compounds) as needed. A target compound is defined as one that is assigned by the Project Officer for synthesis, purity evaluation or determination of physico-chemical properties such as stability, solubility characteristics and spectroscopic data.

### **2. Description of Work**

The Contractor shall perform the following functions:

- a. Provide and operate a chemical synthesis laboratory to prepare samples of assigned chemical compounds and as necessary carry out process development required to obtain those compounds.
  - b. Provide price and time estimates required for completing the synthesis.
  - c. Prepare the assigned compounds on a scale commensurate with the sample size requested. Most often the initial synthetic procedure to be used shall be that provided with the assignment, if such is available. The Project Officer's approval is required for deviations which involve a change in the synthetic route. When no specific procedure or suggested synthetic route is provided for an assignment, the Contractor shall furnish one for the Project Officer's approval prior to starting work.
- (1) Arrange synthesis assignments to fit the priorities assigned by the Project Officer.
- e. Deliver assigned synthesis targets to the NCI in agreed upon amounts generally in the range of 100 mg to 100 gram, and within agreed upon time frames.

- f. Provide samples of intermediates and characterized by-products to the NCI as requested by the Project Officer.
- g. Characterize compounds to be submitted to NCI for purity by a chromatographic method, and for chemical identity by  $^1\text{H}$  NMR, IR, UV, elemental analysis, and when requested, by MS and/or  $^{13}\text{C}$  NMR.
- h. Provide data sheets and preparative methods for all materials sent to NCI. The description of preparative methods shall be sufficiently detailed to permit others to use them as directions for the preparations.
- i. Provide Material Safety Data Sheets (MSDS) for all compounds delivered to NCI in accordance with the attached format. (FIGURE 1)
- j. Provide detailed time and materials cost data for specific assigned compounds.
- k. On specific assignment from the Project Officer:
  - (1) Procure and further characterize compounds available from commercial sources.
  - (2) Perform storage stability studies on selected assigned compounds to help select storage and/or shipping conditions.
  - (3) Perform solubility determinations on selected assigned compounds.

#### **D. SAFETY**

- 1. The compounds targeted for synthesis should be considered toxic and shall be handled accordingly. Thus, the synthetic chemists shall routinely use optimally working hoods, disposable gloves, dust masks, aprons, and related protective gear.
- 2. The Contractors are expected to comply with OSHA regulations including those promulgated by the Secretary of Labor under the Williams-Steiger Occupational Safety and Health Act of 1970. A determination of compliance shall be made before award.
- 3. The Contractors are expected to be in compliance with Environmental Protection Agency regulations regarding the discharge of water and air pollutants and for assuring that disposal of all chemical residues meet current EPA regulations.

#### **E. HUMAN SUBJECTS**

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractors or made available by them for use by anyone other than the Government, for experimental or therapeutic use on humans without the prior written approval of the Contracting Officer.

## **F. CONFIDENTIALITY INFORMATION**

In accordance with HHSAR clause 352.224-70 “Confidentiality of Information” certain data provided to the contractor under this contract must be treated confidentially. The data to be treated confidentially are associated with certain “discreet” compounds which are not available to the public because, for example, the owner may be in the process of obtaining a patent or the compound may be protected by a patent. Confidential information includes but is not limited to the identity of suppliers, compound structures, amounts being prepared etc. When compounds are assigned to the contractor for synthesis or purity evaluations, these discreet compounds will be identified by the letter “D” as a prefix to the NSC number of the compound.

Figure 2

### Summary Project Progress Report

For month:\_\_\_\_\_ Yr:\_\_\_\_\_

Chemical name:	Date prepared:
Chemical Formula:	Contract no:
Structure:	NSC no:
	Date assigned:
	Target amount:
	Report submitted By:
	Priority no:
	Note book ref:
	Literature ref:
Synthetic route:	
Synthesis has progressed to:  Comments:	
Discussions:	

## MATERIAL SAFETY DATA SHEET

Organizational Name :  
Address:

NSC No:

Revision Date:

### SECTION I. MATERIAL IDENTIFICATION

Common Name:

CAS:

Chemical Name:

Molecular Weight:

Molecular Formula:

Other Designations:

### SECTION II. INGREDIENTS AND HAZARDS

Ingredient Name	Percent	Exposure Limits
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	100%	
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Toxicity Data:

To the best of our knowledge the toxicological properties have not been fully investigated.

### SECTION III. PHYSICAL DATA

Appearance & Odor:

MP:

BP:

Solubility (%) / Solvent :

Other Physical Data:

#### SECTION IV. FIRE AND EXPLOSION DATA

Flash Point:	Autoignition Temperature:
Flammability Limits:	LEL %: N UEL %:
Extinguishing Media:	Water, carbon dioxide, or dry chemical as appropriate to the surrounding fire.
Unusual Fire or Explosion Hazards:	No unusual fire or explosion hazard is known to exist.
Special Fire-fighting Procedures:	Evacuate personnel to a safe area. Fire fighters should use protective clothing and a self-contained breathing apparatus.
Hazardous Combustion Products:	Thermal decomposition may produce carbon monoxide and other toxic substances. Since specific products of combustion are unknown, as a precaution, assume they are hazardous.

#### SECTION V. REACTIVITY DATA

Compound Stability:	Material is stable under most conditions. Hazardous polymerization is not known to occur.
Chemical Incompatibilities:	No unusual chemical incompatibilities are known to exist.
Conditions To Avoid:	No conditions contributing to instability are known to exist.
Hazardous Decomposition Products:	Since products of decomposition are not known, as a precaution, assume they are hazardous.

#### SECTION VI. HEALTH HAZARD INFORMATION

Summary of Risks:	The carcinogenicity and teratogenicity of are unknown. Other risks...
Primary Entry Routes:	Inhalation, ingestion, and skin and/or eye contact.
Target Organs:	The target organs of toxicity are not known at this time.
Medical Conditions Which May Be Aggravated By Contact:	UNKNOWN
Signs & Symptoms of Overexposure:	The effects of overexposure to this drug in the workplace are not known at this time.
Acute Effects:	Chronic Effects:
For Eye Contact:	Immediately flush eyes with copious amounts of water for at least 15 minutes. Consult an ophthalmologist.
For Skin Contact:	Remove contaminated clothing. Wash skin with plenty of soap and water. Consult a physician. Chemically decontaminate clothing and then launder before reuse or incinerate.
For Inhalation:	Remove victim promptly to clean air. Administer artificial respiration if victim is not breathing. If breathing is difficult give oxygen. Consult a physician.

For Ingestion: Remove residual drug. Consult a physician. Provide supportive treatment. No specific antidote exists.

## **SECTION VII. SPILL, LEAK AND DISPOSAL PROCEDURES**

Spill/Leak Cleanup Procedures: Evacuate area. Wear self-contained breathing apparatus, rubber boots, and heavy rubber gloves. Wear disposable coveralls and discard after use. Avoid raising aerosols by promptly covering the spilled compound with wet paper towels. Pick up compound with additional towels, place in a bag, and hold for waste disposal. Ventilate area and wash spill site after compound pick-up is complete. Dispose of contaminated clean-up materials properly.

Waste Management/Disposal: Incineration is the preferred method of disposal. Observe all Federal, state, and local laws concerning the disposal of hazardous material or waste.

## **SECTION VIII. SPECIAL PROTECTION INFORMATION**

Personal Protective Equipment:

Goggles: Wear chemical safety goggles when handling  
Gloves: Wear rubber or latex gloves when handling  
Respirator: Wear NIOSH-MSHA approved respirator.  
Other: Wear protective laboratory coat.

Workplace Considerations:

Ventilation: Laboratory operations should be conducted in a chemical fume hood, glove box, or ventilated cabinet equipped with mechanical exhaust to the outside.

Safety Stations: Safety shower and eye bath should be accessible.

The personal protective equipment listed above should be worn at all times when handling. Avoid contact and inhalation. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

## **SECTION IX. SPECIAL PRECAUTIONS**

Storage Segregation: Store in a tightly-closed container at

Other Precautions: The user should be made aware that this is an investigational substance. Handling as solids or solutions should be carried out with extreme care to avoid personal exposure. Hazards associated with exposure to may as yet be unknown. This material should be handled only by those trained in the handling of potentially hazardous material.

For Non-Emergency Information contact:

Decontamination Procedures

Material Safety Data Sheets

Toxicity Data

For emergency information call:



The information in this document was compiled primarily from secondary sources. The information is believed to be correct and accurate, but no warranty is expressed or implied.